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April 21, 1999

Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20857

Re: **Docket No. 98P-0493/PSA1& RC1 –180 Day Generic Exclusivity for Tamoxifen**

Dear Sir or Madam:

As I have stated in earlier correspondence, I was Counsel to the Generic Pharmaceutical Industry Association (GPIA) in 1984 and was the originator of the provisions of the 1984 Drug Price Competition Act relating to the 180 days of generic exclusivity accorded to ANDAs containing paragraph IV patent certifications. In writing this letter, I speak only for myself. I do not represent anyone and am not being paid by anyone. I write solely because I believe I have an obligation to make my expertise with respect to the '84 Act available to protect the public interest.

I am writing to request clarification of the FDA letter of March 2, 1999 which concludes that "the effective date of approval of any ANDA for Tamoxifen Citrate other than the one submitted by Barr Laboratories, Inc. until 180 days after the date of the first commercial marketing of the drug under Barr's ANDA, or the date of a final decision of a court holding the tamoxifen patent to be invalid or not infringed." In all likelihood, neither of the two conditions will occur before the tamoxifen citrate patent expires. Therefore, if the FDA ruling were taken literally, it would prohibit third parties from obtaining ANDA approvals to commence marketing on the expiration date of the tamoxifen patent. I respectfully submit that such a ruling would be a clear violation of the language and intent of Congress in enacting the Drug Price Competition Act of 1984.

One of the principle purposes of the '84 Act was to insure that generic competition would begin on the day on which patent protection expired. This was the basic purpose of the so called "Bolar" exemption, 35 USC § 271 (e)(1) which made it possible to do the work necessary to obtain approval for an ANDA prior to patent expiration without being charged with patent infringement.

The patent certification provisions incorporated into Title I of the '84 Act were designed and intended to permit approval of an ANDA before the listed patent expiration date in those circumstances where a patent was successfully challenged. They were also intended to give the first patent challenger a commercial headstart over subsequent challengers. However, there is nothing in the language of these patent challenge

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provisions which can properly be construed to deprive the public of full-fledged generic competition on the day that patent coverage expires.

The operative language of 21 USC § 355 (j)(4) (B) reads as follows:

> (B). The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection **shall** be made effective on the last applicable date determined under the following:
>
> (i) If the applicant only made a certification described in clause (I) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.
>
> (ii) **If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii). (Emphasis added)**
>
> (iii) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. *******
>
> (iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing [sic] such a certification, the application shall be made effective not earlier than one hundred and eighty days after-
>
> > (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
> > (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

Clearly, clause (B)(ii) mandates approval of any ANDA containing a Paragraph (iii) certification, i.e., a certification seeking approval as of the expiration date of a listed patent, to be approved on the date the listed patent expires. Nothing in the generic exclusivity clause (B)(iv) alters that conclusion. Indeed, the statutory language authorizing the 180-day exclusivity only deals with the issue of when a second (or subsequent) ANDA containing a paragraph (iv) certification can be approved in those instances where there is a prior ANDA containing a paragraph (iv) certification. It presumes the existence of an unexpired patent since the issues of patent validity and infringement become moot after expiration except in cases involving commercial infringement where damages are being sought for past commercial acts. There is simply no basis for construing clause B (iv) as overriding clause B (ii) particularly since B (iv) has no apparent applicability to ANDAs containing paragraph (iii) certifications.

The entire purpose of the 180-day exclusivity provision was to reward a patent challenger for the public benefit which accrues as a result of commencing the sale of a lower cost generic drug at a date earlier than the patent expiration date. A construction of

the '84 Act which prevents unfettered competition after patent expiration would produce a public detriment. Given the Bolar exemption and the other legislative history which clearly establishes the intent of Congress to encourage the availability of generic drugs at the earliest possible moment, it would be a grievous error on the part of the FDA to construe the statue in a manner which delayed such availability unless the language of the statute unequivocally mandated such a result. It clearly does not. The only logical way to construe the '84 Act which is consistent with its language as well as with common sense is to conclude that all ANDAs containing paragraph (iii) certifications become approvable under paragraph B (ii) when the listed patents expire.

For the foregoing reasons, it is respectfully requested that the FDA issue a supplemental response to the petition which clearly indicates that ANDAs containing paragraph iii certifications will be approved as of the expiration date of the tamoxifen citrate patent irrespective of whether Barr has enjoyed 180 days of exclusivity prior to that date.

Sincerely,

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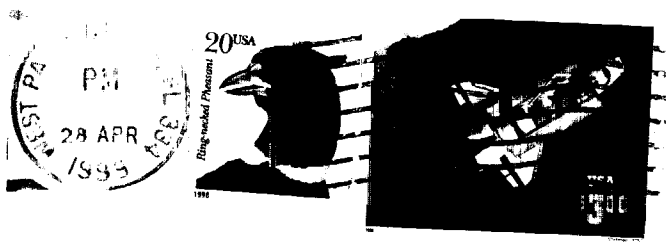

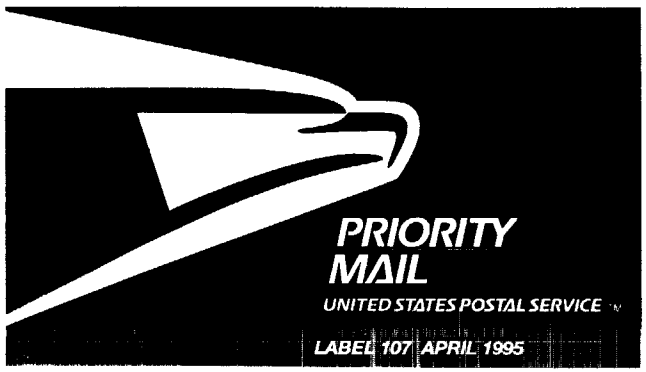

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